DOCKET NO.: UPAP-0497 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: **David B. Weiner, Bin Wang and Kenneth E. Ugen**

Serial No.: **Not Yet Assigned** Group Art Unit: **Not Yet Assigned**

Filed: **Herewith** Examiner: **Not Yet Assigned**

For: **METHODS OF INDUCING MUCOSAL IMMUNITY**

EXPRESS MAIL LABEL NO: EL 884783757 US
DATE OF DEPOSIT: February 14, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

PRELIMINARY AMENDMENT

This preliminary amendment is being filed together with the above-identified application which is a continuation application of Application Serial No. 08/357,398 which has been allowed. Please amend the application as follows.

IN THE SPECIFICATION:

Between the title and the "Field of the Invention" section, please insert the following section heading and paragraph:

"Cross Reference to Related Applications

This application is a continuation of Application Serial No. 08/357,398, allowed."

IN THE CLAIMS:

Please cancel claims 1-14 and insert new claims 15-38 in their place as follows.

15 (New). A method of inducing in an individual a therapeutically effective immune response against an antigen

wherein said therapeutically effective immune response includes both a humoral immune response that includes a mucosal immune response and a cellular immune response that includes antigen specific cytoxic T lymphocytes;

the method comprising the step of administering by topical or lavage administration to mucosal tissue of said individual, said mucosal tissue is selected from the group consisting of rectal, vaginal, urethral, sublingual and buccal, a nucleic acid molecule that comprises a nucleotide sequence that encodes said antigen operably linked to regulatory sequences in an amount effective to induce a therapeutically effective immune response against said antigen which said therapeutically effective immune response which includes both a humoral immune response that includes a mucosal immune response and a cellular immune response.

16 (New). The method of claim 15 wherein the antigen is a pathogen antigen.

17 (New). The method of claim 15 wherein said nucleic acid molecule is administered vaginally.

18 (New). The method of claim 17 wherein the antigen is a pathogen antigen.

19 (New). The method of claim 17 wherein said nucleic acid molecule is administered using a suppository.

20 (New). The method of claim 15 wherein said nucleic acid molecule is administered rectally.

21 (New). The method of claim 20 wherein the antigen is a pathogen antigen.

22 (New). The method of claim 20 wherein said nucleic acid molecule is administered using a suppository.

23 (New). The method of claim 15 wherein said nucleic acid molecule is administered sublingually.

24 (New). The method of claim 23 wherein the antigen is a pathogen antigen.

25 (New). The method of claim 15 wherein said nucleic acid molecule is administered into buccal tissue.

26 (New). The method of claim 25 wherein the antigen is a pathogen antigen.

27 (New). A method of inducing in an individual a prophylactically effective immune response against an antigen

wherein said prophylactically effective immune response includes both a humoral immune response that includes a mucosal immune response and a cellular immune response that includes antigen specific cytoxic T lymphocytes;

the method comprising the step of administering by topical or lavage administration to mucosal tissue of said individual, said mucosal tissue is selected from the group consisting of rectal, vaginal, urethral, sublingual and buccal, a nucleic acid molecule that comprises a nucleotide sequence that encodes said antigen operably linked to regulatory sequences in an amount effective to induce a prophylactically effective immune response against said antigen which said prophylactically effective immune response which includes both a humoral immune response that includes a mucosal immune response and a cellular immune response.

28 (New). The method of claim 27 wherein the antigen is a pathogen antigen.

29 (New). The method of claim 27 wherein said nucleic acid molecule is administered vaginally.

30 (New). The method of claim 29 wherein the antigen is a pathogen antigen.

31 (New). The method of claim 29 wherein said nucleic acid molecule is administered using a suppository.

32 (New). The method of claim 27 wherein said nucleic acid molecule is administered rectally.

33 (New). The method of claim 32 wherein the antigen is a pathogen antigen.

34 (New). The method of claim 32 wherein said nucleic acid molecule is administered using a suppository.

35 (New). The method of claim 27 wherein said nucleic acid molecule is administered

sublingually.

36 (New). The method of claim 35 wherein the antigen is a pathogen antigen.

37 (New). The method of claim 27 wherein said nucleic acid molecule is administered into buccal tissue.

38 (New). The method of claim 37 wherein the antigen is a pathogen antigen.

REMARKS

This preliminary amendment is being filed together with the above-identified application which is a continuation application of Application Serial No. 08/357,398.

Claims 1-14 are in the application.

By way of this preliminary amendment, the specification is amended, claims 1-14 are canceled and new claims 15-38 are added.

Upon entry of this preliminary amendment, claims 15-38 will be pending.

The specification is amended to include the necessary reference to the parent application. No new matter is added.

The claims are amended to more clearly define embodiments of the invention. Support

for the new claims is found throughout the specification and claims as originally filed. No new matter is added.

Claims 15-38 are in condition for allowance. A notice of allowance is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Respectfully submitted,

Mark DeLuca
Registration No. **33,229**

Date: 2/14/02

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Between the title and the "Field of the Invention" section, a Cross Reference to Related Applications section heading and paragraph were added.

IN THE CLAIMS:

Claims 1-14 have been canceled and new claims 15-38 have been added.